The clinical validation of a dried blood spot method for immunosuppressive drugs and creatinine

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23332

Source
NTR

Brief title
VIDA study

Health condition

Transplant recipients

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Optimizing the correction factor needed and clinically validating a DBS method for tacrolimus, everolimus, sirolimus, ciclosporin and creatinine.

Secondary outcome

- Analyzing the differences in the measured concentrations in the dried blood spot made with blood obtained from venous sampling and capillary sampling.
- Evaluating the need of a correction factor when measuring the hematocrit in the DBS samples
- Analyzing the difference between the drug concentration in the microtainer and filtrate card, to investigate the influence of the filtrate card on the drug concentration

Study description

Background summary

Rationale: Transplant rejections can occur when a patient is not properly adjusted on immunosuppressive drugs. The great interpatient pharmacokinetic variability of immunosuppressive drugs, can lead to under- and overexposure with serious consequences. To ensure adequate exposure to immunosuppressive drugs, drug doses are adjusted based on whole-blood concentration measurements, a practice known as therapeutic drug monitoring (TDM). A sampling method for TDM that has become more popular over the recent years is dried blood spotting (DBS). DBS is a design of blood sampling consisting of positioning a drop of capillary blood, preferably taken from the finger, on filter paper. Unlike venous blood sampling (the current gold standard for TDM immunosuppressive drugs), DBS seems to have advantages for the patient. The finger prick is less invasive than venipuncture. DBS also enables patients to perform one or multiple finger prick(s) themselves, which may result in less frequent hospital visitations and the possibility to sample at multiple time points. Due to the fact that the cornerstone of immunosuppression, tacrolimus, everolimus, sirolimus and ciclosporin are nephrotox and are prescribed to maintain adequate kidney transplant function, it would be very efficient and convenient to measure creatinine in the same dried blood spot as the immunosuppressants.
Objective: The objective of this study is to clinically validate a DBS method for immunosuppressive drugs and creatinine, using a LC-MS/MS method.
Study design: Cross-sectional observational study.
Study population: Forty patients aged 18 or over, will be included for each of the four drugs, (tacrolimus, everolimus, sirolimus and ciclosporin), i.e. 160 patients in total.
Intervention (if applicable): Patients are treated with tacrolimus, everolimus, sirolimus or ciclosporin, in the dose prescribed by their treating physician. In addition to the standard venous samples, DBS samples will be collected by a trained student or nurse from patients visiting the hospital for periodic check-ups.
Main study parameters/endpoints: Correlation between the DBS concentrations and venous blood concentrations of immunosuppressive drugs and creatinine.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: After receiving informed consent from the patients, a finger prick for both the filtrate paper and microtainer will be performed in addition to the standard venipuncture. A finger prick carries a minimal risk of complications. This intervention may cause mild pain or

local irritation. During the study, the participating patients will have no benefits. The blood samples will be drawn by a nurse or trained researcher during regular hospital visits. Secondly, after the collection of the blood samples a short questionnaire will be taken, with four questions, assessing the patients' experience of the DBS method in comparison to venipuncture. When the method is successfully validated, DBS may be of great benefit to a larger group of patients that use immunosuppressive drugs.

Study objective

Concentration of immunosuppressive drugs and creatinine could be measured using dried blood spot

Study design

Predose level

Intervention

Patients are treated with tacrolimus, everolimus, sirolimus or ciclosporin, in the dose prescribed by their treating physician. In addition to the standard venous samples, DBS samples will be collected from patients visiting the hospital for periodic check-ups.

Contacts

Public
Erasmus Medical Center
Brenda de Winter

+31107033202
Scientific
Erasmus Medical Center
Brenda de Winter

+31107033202

Eligibility criteria

Inclusion criteria

- Aged 18 and over
- Able to understand written information and able to give informed consent

- Treated with tacrolimus, everolimus, sirolimus and/or ciclosporin
- Able and willing to undergo a finger prick for dried blood spot sampling
- Able and willing to fill in a questionnaire

Exclusion criteria

- Unable to draw blood samples for study purposes

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-04-2020
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-04-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8502
Other	METC Erasmus MC : MEC-2019-0783

Study results